DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 3, 2015

Thinkmed Medical Technology Co., Ltd.
Garfield Wang
General Manager
No.4 Building, 322 Hongyang Road
Qiandeng Town, Kunshan City 215341
China

Re: K142767
Trade/Device Name: Thinkmed Intermittent Catheter with/without Hydrophilic Coating
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: January 4, 2015
Received: January 7, 2015

Dear Garfield Wang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section_004 Indications for Use

510(k) Number (if known): K142767

Device Name: ThinkMed Intermittent Catheter with/without Hydrophilic Coating

Indications for Use

The ThinkMed Intermittent Catheter with/without Hydrophilic Coating is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder - voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.

Prescription Use ___√___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section_005 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: 15. 01.2015

1. Submitter Name and Address:

Owner Name: ThinkMed Medical Technology Co., Ltd.
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US Agent:
Name: CARELIFE (USA) INC.
Address: 1580 Boggs Rd, Suite 500/600 Duluth GA 30096
TEL: 404 6612228
Contact person : Ms. LI QIAN liqian@shanghaicarelife.com

2. Submission Devices Information:

Trade/Proprietary Name: ThinkMed Intermittent Catheter with/without Hydrophilic Coating
Common Name: Intermittent Urethral Catheter
Classification name: Urological catheter and accessories
Class: 2.
Product codes: GBM
Submission Type: 510(k)
Regulation Number: 876.51306

3. Predicate Devices Information:

Trade Name: BEVER Intermittent Catheter
510(K) Number: K111405
Submitter: Hangzhou Bever Medical Devices Co., Ltd

4. Devices Description:

ThinkMed Intermittent Catheter is sterile, single use device to be designed as an intermittent pathway for drainage of the bladder. It is available for male and female, in uncoated and coated variants and in two different tip configurations of Nelaton (straight and rounded) and Tiemann (curved and tapered) respectively. There are two polished drainage eyelets on the catheter in various configurations and types.

The uncoated catheter is manufactured with conventional medical grade, latex-free, biocompatible materials. it is consists of a tubular catheter shaft with attached a drainage funnel.

The catheter is available in sizes 6Fr to 22Fr for Nelaton-tip and sizes 8Fr to 22Fr for Tiemann-tip.

The coated catheter is manufactured with conventional medical grade, latex-free, biocompatible materials. Coated with a hydrophilic low-friction coating, with attached a drainage funnel. The surface of coated catheter is hydrophilic and when the coated catheter is activated with the sterile water, it becomes slippery and thus reduces friction against the urethra. This allows the coated catheter to slide in and out of the urethra in the most comfortable way.
The coated catheter is available in sizes 6Fr to 22Fr for Nelaton-tip and sizes 8Fr to 22Fr for Tiemann-tip.

5. Intended Use:

The ThinkMed Intermittent Catheter with/without Hydrophilic Coating is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder - voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.

6. Technological Characteristics:

Through comparisons between the submitted devices with the predicate devices as follows tables. We believe the applicant devices are substantially equivalent with the predicate devices.

Comparison Table

Element of Comparison	Submission Device	Predicate Device K111405
Intended Use	The ThinkMed Intermittent Catheter with/without Hydrophilic Coating is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder - voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.	The BEVER Intermittent Catheter is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder - voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.
Condition of Use	Single Use	Single Use
Principle of Operation	intermittent catheterization	intermittent catheterization
Prelubricated	NO	Yes-by sterile water
End Design	Funnel	Funnel
Tip Design	Nelaton & Tiemann	Nelaton & Tiemann
Hydrophilic Coating	polyvinylpyrollid	polyvinylpyrollid
Sterilization	EtO Gas	EtO Gas

Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

7. Non-Clinical Test Conclusion:

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F 623 Standard performance specification for foley catheter.

The ThinkMed Intermittent Catheter with/without Hydrophilic Coating maintains the same intended use as the predicate devices. It is a device that is inserted through the urethra and used to drain urine from the bladder.

The ThinkMed Intermittent Catheter with/without Hydrophilic Coating is composed essentially of the same materials as the predicate devices.

The ThinkMed Intermittent Catheter with/without Hydrophilic Coating has the same design and performance characteristic as the predicate devices.

The dimension, design, material, sterility, packaging and labeling of ThinkMed Intermittent Catheter with/without Hydrophilic Coating are conformed with ASTM F 623.

8. Biocompatibility Test:

Biocompatibility testing was performed based on ISO 10993 requirements. The indwell time of ThinkMed Intermittent Catheter with/without Hydrophilic Coating is about 1-3 minutes. And it contact mucosal membrane. The Cytotoxicity, Sensitization and Irritation biocompatibility tests were performed on ThinkMed Intermittent Catheter with Hydrophilic Coating. The tests indicated that the ThinkMed Intermittent Catheter is biocompatible and safe for its intended use.

9. Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent.

END